DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 21, 2015

Medtronic Sofamor Danek USA, Incorporated
Ms. Shweta Sharma
Senior Regulatory Affairs Specialist
1800 Pyramid Place
Memphis, Tennessee 38132

Re: K141599
Trade/Device Name: DIVERGENCE™ Anterior Cervical Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: December 23, 2014
Received: December 24, 2014

Dear Ms. Sharma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141599

Device Name
DIVERGENCE™ Anterior Cervical Fusion System
(For Stand-Alone Interbody Device Only)

Indications for Use *(Describe)*

The DIVERGENCE™ Anterior Cervical Fusion System consists of a stand-alone interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The DIVERGENCE™ stand-alone cervical interbody device must be used with internal screw fixation. The DIVERGENCE™ stand-alone cervical interbody device is also required to be used with autogenous bone graft and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DIVERGENCE™ Anterior Cervical Fusion System
510(k) Summary

January 2015

I.	**Company**	Medtronic Sofamor Danek USA, Inc. 1800 Pyramid Place Memphis, TN 38132 (901) 396-3133
II.	**Contact**	Shweta Sharma Senior Regulatory Affairs Specialist
III.	**Proprietary Trade Name**	DIVERGENCE™ Anterior Cervical Fusion System
IV.	**Common Name**	Cervical Intervertebral Fusion Device with Bone Graft
V.	**Classification Name**	21 CFR 888.3080 - Intervertebral Body Fusion Device
	Classification	Class II
	Product Codes	OVE
	Primary Predicate	PEEK PREVAIL® Cervical Interbody Device (K113252, SE 01/17/2012)
	Secondary Predicates	•CORNERSTONE® PSR Cervical Fusion System (K111264; K100214) •AFFINITY® Anterior Cervical Cage System (P000028, down-classified to Class II special controls, Date of Final Order 06/12/2007) •ZEPHIR® Anterior Cervical System (K030327) •ATLANTIS® Anterior Cervical Plate

System (K130640)

VI. Product Description

The DIVERGENCE™ Anterior Cervical Fusion System consists of a stand-alone interbody fusion device with internal screw fixation. The DIVERGENCE™ Anterior Cervical Fusion System is indicated for anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. This system is indicated for single-level use only in the C2-T1 anterior spine. The system is comprised of a PEEK interbody cage and screws.

The DIVERGENCE™ anterior cervical cages are provided in 0 and 6 degrees of lordosis, 5-12mm heights, 15-20mm widths and 12-16mm depths. This device is intended to be radiolucent, and the interior space of the product is to be used with autogenous bone graft. The DIVERGENCE™ stand-alone cervical interbody device is manufactured from medical grade polyetheretherketone (PEEK) and contains radiopaque markers made from medical grade titanium alloy. The PEEK interbody cage also comes preassembled with a titanium alloy, built-in rotary locking mechanism.

The bone screws used with this device are provided in self-drilling and self-tapping options and are manufactured from medical grade titanium alloy. The bone screws are provided in 3.5mm and 4.0mm diameters and 9-17mm lengths.

The PEEK material (PEEK OPTIMA™ LT-1) used conforms to ASTM F2026 and the titanium alloy material (Ti-6Al-4V ELI) used conforms to ASTM F136 standards. These devices are offered in sterile form.

VII. Indications for Use

The DIVERGENCE™ Anterior Cervical Fusion System consists of a stand-alone interbody device indicated for use in anterior cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc

to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. The DIVERGENCE™ stand-alone cervical interbody device must be used with internal screw fixation. The DIVERGENCE™ stand-alone cervical interbody device is also required to be used with autogenous bone graft and is to be implanted via an open, anterior approach. This cervical device is to be used in patients who have had six weeks of non-operative treatment. Patients with previous non-fusion spinal surgery at involved level may be treated with the device.

VIII. Summary of Technological Characteristics

The subject DIVERGENCE™ Anterior Cervical Fusion System interbody cage component has the same fundamental scientific technology as the predicate PEEK PREVAIL® Cervical Interbody Device, CORNERSTONE® PSR Cervical Fusion System and AFFINITY® Anterior Cervical Cage System. The subject interbody cage is manufactured from the same PEEK and titanium alloy material as the predicate devices. The predicate and subject devices are also both interbody devices designed to contain graft material and facilitate a fusion between two vertebral bodies.

The subject DIVERGENCE™ Anterior Cervical Fusion System bone screws have the same fundamental scientific technology as the predicate ZEPHIR® Anterior Cervical System and ATLANTIS® Anterior Cervical Plate System screws. The subject devices are manufactured from the same titanium alloy material as the predicates. In both predicate and subject devices, fixation is provided by bone screws inserted into the vertebral body of the cervical spine.

IX. Identification of Legally Marketed Predicate Devices Used to Claim Substantial Equivalence

The subject interbody cage is substantially equivalent to the predicates:

- PEEK PREVAIL® Cervical Interbody Device (K113252, SE 01/17/2012; K094042, SE 06/30/2010)
- CORNERSTONE® PSR Cervical Fusion System (K111264, SE 10/12/2011; K100214, SE 06/25/2010)
- AFFINITY® Anterior Cervical Cage System (P000028, Approval Date 06/13/2002, down-classified to Class II special controls, Date of Final Order 06/12/2007)

The subject bone screw is substantially equivalent to the predicates:

- ZEPHIR® Anterior Cervical System (K030327, SE 02/26/2003)
- ATLANTIS® Anterior Cervical Plate System (K130640, SE 06/04/2013)

X. Brief Discussion of the Non-Clinical Tests Submitted

The subject DIVERGENCE™ Anterior Cervical Fusion System devices were tested in accordance with ASTM F2077-11 "Test Methods For Intervertebral Body Fusion Devices" for static and dynamic compression, static and dynamic compression shear, and static and dynamic torsion testing, and ASTM F2267-04(2011) "Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression" for subsidence testing.

The subject devices met the pre-determined acceptance criteria for all the tests. The test results are provided to demonstrate that the subject devices are substantially equivalent to the predicate devices.

XI. Conclusions Drawn from the Non-Clinical Tests

Based on the non-clinical test results and additional supporting documentation provided in this pre-market notification, the subject devices demonstrated substantial equivalence to the listed predicate devices.